DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-591/S-023

Hoffmann-La Roche, Inc.
Attention: Ms. Lynn DeVenezia-Tobias
Program Manager
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated November 9, 2007, received November 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lariam® (mefloquine hydrochloride) Tablets, 250 mg.

This supplemental new drug application provides for addition of new information to the **ADVERSE REACTIONS/Postmarketing** subsection and the **OVERDOSAGE** section of the Lariam labeling to include information on pneumonitis, of possible allergic etiology, which was observed in post-market data.

The following revisions (~~strikethrough~~ = deleted and underlined = added) to the text for the package insert for Lariam were proposed in this supplemental application:

1. The following was added alphabetically under "Other infrequent adverse events include:" in the **ADVERSE REACTIONS/Postmarketing** subsection:

   Respiratory Disorders: dyspnea, pneumonitis of possible allergic etiology

2. The **OVERDOSAGE** section was modified as follows:

   Symptoms and Signs

   In cases of overdosage with Lariam, the symptoms mentioned under **ADVERSE REACTIONS** may be more pronounced.

   Treatment

   ~~The following procedure is recommended in case of overdosage: Induce vomiting or perform gastric lavage, as appropriate.~~ Patients should be managed by symptomatic and supportive care following Lariam overdose. There are no specific antidotes. Monitor cardiac function (if possible by ECG) and neuropsychiatric status for at least 24 hours. Provide symptomatic and intensive supportive treatment as required, particularly for cardiovascular disturbances.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 19-591/S-023**."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Kristen Miller, Pharm.D., Safety Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Renata Albrecht

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